Advanced Pumping Techniques

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and John Walsh, PA, CDTC

See slides at www.diabetesnet.com/presentations/

Pump Advantages

- Convenience
- Easier to match varying needs
- Less insulin stacking
- Lower A1c, less severe hypoglycemia, less BG variability *
- More freedom of lifestyle
- Better data (clinicians, pumpers, parents)


Line Pumps

- Asante Snap
- Tandem t:slim
- Animas Ping
- Medtronic Revel
- Accu-Chek Combo

Patch Pumps

- Valeritas V-Go
- CellNovo
- Accu-Chek Solo
- Insulet Omnipod
- Calibra Finesse

Early Closed Loop – Medtronic 530G

- Low Glucose Suspend (LGS) – CGM can suspend basal up to 2 hrs for a low.
- May reduce length of night lows.
- 6 day Enlite sensor
- CGM alarm excess and wear-ability may be an issue for some

Dexcom – Animas Vibe or Tandem t:slim

- High contrast color screens
- 1 week Dexcom G4 sensor
- Internet access via Diasend or t:connect software
- No low glucose suspend

FDA approvals pending ~2-8 mos?
Accu-Chek and Omnipod CGMs

Accu-Chek CGM has 4 sensor areas on each sensor
- Mean ARD is ~9.2%, compared to ~10.7% for upcoming Dexcom Gen4 algorithm and 13.9% for Enlite.

Omnipod is developing its own CGM system

Navigator II CGM

- Available in UK, Germany, Scandinavia, Holland & Israel
- Sensor is 40% smaller than Navigator
- 1 min updates on BG
- 5 day use with 4 cal's on day one and one more on day 3
- Projected low and high

CGM Advances

- Factory calibration
- Abbott Flash
- Intermittent CGM, test strip pricing
- Dual sensors on one set
- 2 glucose oxidase
- 1 glucose oxidase and 1 fluorescent
- CGM on infusion set cannula
- 6-8 sensors on cannula (15% BG drop)

Remote Control

Advantages:
- Allows discreet bolusing (and basaling in some)
- BG and bolus doses sent via radio wave or Bluetooth
- Keeps data in one location

Disadvantage:
- Omnipod remote must be present to give boluses

Ideal Home Screen Data

- CGM BG and trendline
- BOB and time left
- Time and date
- Battery life
- Reservoir units
- Basal rate
- Time, basal, reservoir, battery
- Time, date, reservoir, battery
- BOB, BOB time, temp basal
- Time, date, pump connection
- Time, reservoir, battery, CGM trend/BG/arrow/connection
- Time, date, connection

Connectivity

- Bluetooth can be found in
  - Some pumps
  - Some meters and CGMs
  - Most cell phones
  - Activity monitors – FitBit, FuelBand, JawBone, MotoActv, BodyMedia

Integration of devices from different manufacturers is key
- Tidepool, etc.
Background on Pump Doses

Bolus Calculator Settings

<table>
<thead>
<tr>
<th>This Setting</th>
<th>Helps</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basal rates</td>
<td>Sound sleep (~50% of TDD)</td>
</tr>
<tr>
<td>CarbF or I:C ratio</td>
<td>Cover carbs well</td>
</tr>
<tr>
<td>CorrF or ISF</td>
<td>Lower highs safely</td>
</tr>
<tr>
<td>Target glucose</td>
<td>Correct to specific goal</td>
</tr>
<tr>
<td>DIA</td>
<td>Minimize insulin stacking</td>
</tr>
</tbody>
</table>

APP Study – BGs and Basal Rates

<table>
<thead>
<tr>
<th>Glucose, Insulin and Carb Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group</td>
</tr>
<tr>
<td>Avg. Meter BG</td>
</tr>
<tr>
<td>BG Test/Day</td>
</tr>
<tr>
<td>144 mg/dL, 8.0 mmol/L</td>
</tr>
<tr>
<td>181 mg/dL, 10.0 mmol/L</td>
</tr>
<tr>
<td>227 mg/dL, 12.6 mmol/L</td>
</tr>
<tr>
<td>144 mg/dL, 8.0 mmol/L</td>
</tr>
<tr>
<td>TDD</td>
</tr>
<tr>
<td>Basal %</td>
</tr>
</tbody>
</table>

APP Study – Carb Boluses and CarbFs

<table>
<thead>
<tr>
<th>Glucose, Insulin and Carb Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group</td>
</tr>
<tr>
<td>Avg. Meter BG</td>
</tr>
<tr>
<td>CarbBolus Und</td>
</tr>
<tr>
<td>184 mg/dL, 10.2 mmol/L</td>
</tr>
<tr>
<td>144 mg/dL, 8.0 mmol/L</td>
</tr>
<tr>
<td>181 mg/dL, 10.0 mmol/L</td>
</tr>
<tr>
<td>227 mg/dL, 12.6 mmol/L</td>
</tr>
</tbody>
</table>

Basal Tips

- Basals usually make up 45 to 65% of TDD
- Basal rates should be similar, such as between 0.5 to 0.7, or 1.0 to 1.4 u/hr
- Adjust basal rates in small steps (usually 0.025 to 0.1 u/hr) **3 to 8 hours** before the need arises

APP Study – BGs and Basal Rates


APP Study – Carb Boluses and CarbFs


How Many Basal Rates Do You Need?

- Number of basal rates used per day from self-reports of hundreds of pumpers at insulin-pumpers.org
- When a basal is changed, it takes 3-5 hrs to have its full effect. *
- Using more than 5 basals may have little benefit.

APP Study – Carb Factors are Often Incorrect\textsuperscript{1,2}

Carb Factors from 400 pumps were not evenly distributed. People like "magic" numbers – 5, 10, 15, and 20 g/unit. Use formulas to derive accurate pump settings -> better than WAG!

Many people use "magic" numbers as CarbFs!

Check Bolus Recommendations

BOB = remaining glucose-lowering activity from recent boluses
Pumps usually cover carbs fully regardless of BOB
When BOB is larger than your correction bolus, consider taking less than the recommended bolus

With 4.35 u of BOB from an earlier bolus, would you give 2.9 more units for a bedtime snack?

APP Study – Occlusions Worsen Control

<table>
<thead>
<tr>
<th>BG Tertile</th>
<th>Low</th>
<th>Middle</th>
<th>High</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avg BG</td>
<td>146.6</td>
<td>181.6</td>
<td>229.3</td>
</tr>
<tr>
<td>Blocks/month</td>
<td>1.36</td>
<td>3.04</td>
<td>3.57</td>
</tr>
</tbody>
</table>

132 pumps in each tertile; avg. BG for 73 days per pump

APP Study – Unexpected Outcomes

Between low, medium, and high avg. BG groups:
- Basal was 48% of TDD in all groups
- Groups ate same grams of carb and took same number of carb boluses and correction boluses per day
- BG testing had no meaningful impact on glucose – the high BG group tested almost as often as low group
- High BG group used MORE insulin a day
- Occlusions significantly raise avg BG

APP Study – Major Conclusion

Find an accurate TDD and get pump settings from it

\textsuperscript{1} J Walsh, R Roberts, T Bailey: J Diab Science & Technology 2010, Vol 4, #5, Sept 2010

\textsuperscript{2} J Walsh, D Wroblewski, and TS Bailey: Insulin Pump Settings – A Major Source For Insulin Dose Errors, Diabetes Technology Meeting 2007

\textsuperscript{1} J Walsh, R Roberts, T Bailey: J Diab Science & Technology 2010, Vol 4, #5, Sept 2010
Dosing Tips

Help Your Health Care Provider

- Check glucose 6x a day or wear a CGM
- Download and bring your records
- Use the bolus calculator for all boluses, count or measure carbs, and override when needed
- Don’t over-treat lows with carbs nor highs with insulin
- Know when to change your pump settings

Size Up the Problem

- If it ain’t broke, don’t fix it!
- Mild – tweak pump settings or lifestyle
- Moderate – For patterns, use pattern management. Otherwise calculate new TDD and retune pump settings
- Severe – Reset the TDD to an improved TDD (iTDD) to correct problem and select new settings from this iTDD.

Steps To Control

- Stop lows first
- Bolus 15 to 30 min before meals when able
- Periodically check basal/carb bolus balance
- Look for and correct unwanted patterns

Stop Frequent Lows First

- You cannot tell how much excess insulin there is!
- Start with a 5% or 10% reduction in the TDD
- Compare the current TDD to an “ideal” TDD for weight.
  - Divide weight (lbs) by 4 to see what TDD you would use if you have an average sensitivity to insulin

**Example:** Someone who weighs 160 lbs would be expected to have a TDD of 40 units (160/4 = 40).

**Example – Frequent Lows**

41 yo female with A1c = 6.9%

TDD = 50.5 u/d

156 lb/4 = 39.0 u/d
Then Stop Frequent Highs

When your average BG is high with few lows:
Raise TDD by 1% for each 6 mg/dl in BG (or for each 0.2% in A1c) you want to lower your glucose

Example: Amy’s avg TDD is 40 u/day. Her average meter BG is 205 mg/dl with few lows. Her BG goal (average) is 145 mg/dl:

\[
205 \text{ mg/dl} - 145 \text{ mg/dl} = 60 \text{ mg/dl}
\]
\[
60 \text{ mg/dl} \div 6 \text{ mg/dl} = 10\% \text{ rise needed in TDD}
\]
\[
40 \text{ units} \times 1.10 = 44 \text{ units}
\]

Example – Frequent Highs

TDD Before & After Adjustment

Start TDD = 36 u
- Raised basal by 0.05 u/hr all day (+1.2 u/day)
- Lowered carb factor from 1u/13g to 1u/12g (+1.8 u/day)

End TDD = 39 u

Duration Of Insulin Action

Accurate boluses require an accurate DIA

Why Short DIAs Cause Problems

3 hours after a 10 unit bolus, table shows how much BOB a pump thinks is left with each DIA time:

<table>
<thead>
<tr>
<th>Pump’s estimate of Insulin On Board</th>
<th>If DIA is set to:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>3 hr</td>
</tr>
<tr>
<td>Estimated BOB is:</td>
<td>0 u</td>
</tr>
</tbody>
</table>

Always set the DIA from an insulin’s real action time
Do not change DIA to fix control problems

Don’t Set Your DIA Short

A short DIA hides BOB and leads to:
- Hidden insulin stacking
- “Unexplained” lows
- Errors in adjustments of basal rates, carb factors, and correction factors
- Or just ignoring your “smart” pump’s advice

Set DIA for real action time: 4.5 to 6 hrs.
Don’t change your DIA to fix control problems
Clever Pump Trick – Super Bolus – Shift Basal To Bolus

Good for:
- Meals with over 30 to 40 grams of carb
- High BGs

Future: Super Bolus shifts part of the next 2 to 3.5 hrs of basal insulin into the bolus with less risk of a low later. 1, 2

J. Walsh:
September, 2004


How Many Carbs do You Need for a Low?

1. 10 grams for each 80 lbs of weight
2. plus grams = the current BOB* x CarbF

Example:
- Amy weighs 160 lbs = 20 grams of carb
- And she has 2 units of BOB with a CarbF of 8 grams/unit
  2 u  x  8 g/u  =  16 grams
- For this low she needs:
  20 g + 16 g = 36 grams
  Add extra carbs as needed for recent or planned exercise.

Infusion Set Issues

- Little research has been done
- Clinician and wearer reports and blogs suggest infusion set issues are widespread
- Set leaks and failures create random hyperglycemia, making their source difficult to identify.
- A major source for calls to pump companies and for pump discontinuation
- Less than 10% of inspected pumps have any defect

Infusion Sets – The Achilles Heel Of Pumps

Survey of 1142 pumpers in 40 German diabetes clinics

- 54% reported an increase in glycemia for unknown reasons until their infusion set is changed
- 19% reported kinking, 12% had leakage, 12% air bubbles, and 33% had other issues
- 36% used auto-insertion devices – 72% of them reported that the device failed to work ~10% of the time

Gabriele and Lutz Heinemann: Reality of insulin pump treatment in Germany: Results from a survey with 1142 patients treated in 40 specialized practices
Abstract # 2013 ADA Meeting. winDiab, Scientific Institute of the Specialized Diabetes Practice, Düsseldorf, Germany

Pump Failure Modes

- Most of the 16,849 adverse pump events reported to the FDA between 2006-2009 involved infusion sets: failure, disconnection, or bent cannula
- A 2006 review of pumps in France also found most serious adverse events involved infusion sets: obstruction, leakage, infection, or inflammation
How Long Do People Use Infusion Sets?

Most pump wearers use their infusion sets for 2-3 days.

Do You Have a Set Problem?

- Do sites often “go bad”?
- Do you have “scarring” or “poor absorption”?
- Often have 2 or more unexplained highs in a row?
- Do correction boluses sometimes not work?
- Have high BGs (often 8-32 hrs) until set is changed?

Counter-Measures to Sweat

- Skin-Tac
- Mastisol/Detachol
- Tincture of Benzoin
- Toupee glue

New Developments

Unpublished data from Actual Pump Practices Study by J Walsh, R Roberts, and T Bailey
Implanted CGMs

- Months to years of use
- No disposables
- Minor surgery
- Funded as rental?

Implanted Fluorescent CGM

- Molecules fluoresce & change color as glucose rises or falls
  - Small size, low power, low cost, long life, good accuracy, minimal lag time

From Y. J. Heo et al. Institute of Industrial Science at the University of Tokyo

Faster Insulin

- For better matching of carbs (< 2 hrs) with insulin (5 hrs)
  - Ultra-fast insulin analogs
    - Novo Nordisk FIAsp
    - Biodel
    - MannKind Afrezza (inhaled)
  - Diaport intraperitoneal delivery
  - Micro-needle intradermal delivery
  - Hyaluronidase
  - Warming of infusion site

Goal: fewer highs and lows

Accu-Chek Diaport

- Delivery into the abdominal cavity speeds up insulin action when more insulin goes directly to the liver

BD Intradermal Microneedle

- 1.5 mm intradermal needle speeds up insulin action
- Painless
- Reliable attachment of set will be critical

Hyaluronidase

- Recombinant human hyaluronidase temporarily degrades local hyaluron, a structural protein in the interstitial space
  - Speeds up insulin uptake
  - DIA ~4 to 4.5 hrs?
  - Phase 3 clinical trials underway with release in early 2014?
Future Pump Features

- How setting change impacts TDD (& BG)
- Temp basal plus bolus doses
- Super Bolus
- Meal-size boluses
- Excess BOB alert (bolus without BG but BOB is ++)
- Low BG predictor (HypoManager)
- Exercise compensator
- Infusion set monitor/leak detector
- Automated basal and bolus testing

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